Appendix C – 510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Abbott Vascular (351931722)
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95054
Telephone: Fax:	951-914-2292 951-914-1069
Contact Person: Date Prepared:	Nadine Smith, Regulatory Affairs Associate 11/09/2006
Device Trade Name: Device Common Name: Device Classification:	RX Herculink® Elite™ Biliary Stent System Biliary Stent Class II

SEP 14 2007

Summary of Substantial Equivalence:

The modified RX Herculink Elite™ Biliary Stent System is substantially equivalent to the original RX Herculink Elite Biliary Stent System (K053454, cleared 3/6/2006) and RX Herculink Plus Biliary Stent System (K010684, cleared 4/12/2001). Changes made to the original RX Herculink Elite Biliary Stent System focused primarily on the delivery system.

Device Description:

The modified RX Herculink Elite Biliary Stent System includes:

- A balloon expandable L605 cobalt chromium alloy stent pre-mounted on the balloon of a rapid exchange (RX) stent delivery system;
- Two radiopaque markers located underneath the balloon which identify the stent position and fluoroscopically mark the working length of the balloon;
- Proximal shaft markers to aid with delivery catheter position, relative to a biliary guiding catheter tip;
- A third marker located approximately 30 cm from the center of the balloon that aids in locating the guide wire exit lumen and facilitating catheter removal and exchange.

The delivery system can be utilized to optimize the stent wall apposition post stent deployment.

Summary of Changes to Previously Cleared Device

- The balloon fold configuration for 5.5 and 6.0 mm balloons was changed from Tri-fold (3) to Quad-fold (4)
- The RX Herculink Plus balloon folding process was applied to 4.0 – 6.0mm balloon diameters as appropriate.
- Added Balloon Press to 5.0 – 7.0mm balloon diameters

- Added Balloon Heat Set to all balloon sizes from 4.0-7.0mm balloon diameters
- Added a 100% in process inspection using a USON Sprint Dry Leak Tester. I

Intended Use:

The intended use for the modified device has not changed as a result of the modifications.

The RX Herculink Elite Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

Performance Data:

The results of the *in vitro* bench tests and analyses and biocompatibility testing demonstrated the safety and effectiveness of the modified RX Herculink Elite Biliary Stent System.

Verification and Validation (V & V) Tests:

Verification and Validation testing was performed as relevant to the modifications to the RX Herculink Elite Biliary Stent System as follows:

Table 11 – V&V Summary

Test	Results
Foreshortening, Uniformity of Expansion	Pass Foreshortening and Uniformity of Expansion met the acceptance criteria.
Balloon Rated Burst Pressure (RBP)	Pass The balloon rupture met the acceptance criteria. Labeling 25% above RBP, 17 ATM met the acceptance criteria.
Inflation/ Deflation	Pass Acceptance criteria for the inflation and deflation times were met.
Tensile Strength	Pass The acceptance criterion for the catheter soft tip was met.
Deployment • Accuracy of stent placement • Low pullback resistance of a deflated balloon • Capable of safely removing the delivery system	Pass The acceptance criteria for deployments were met. Comparison Rating - Equal
Overall test device performance rating. Was the function of the test article clinically acceptable for its intended use?	Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2007

Ms. Nadine Smith
Regulatory Affairs Associate
Abbott Vascular
Vascular Solutions
3200 Lakeside Drive
SANTA CLARA CA 95054-2807

Re: K063481
Trade/Device Name: RX Herculink® Elite™ Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: April 4, 2007
Received: April 5, 2007

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

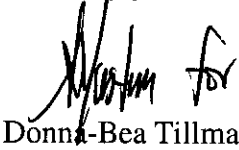
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.H.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K063481

Device Name: RX Herculink® Elite™ Biliary Stent System

FDA's Statement of the Indications For Use for device:

The RX Herculink® Elite™ Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063481